

AWARD NUMBER: W81XWH-15-2-0062

TITLE: Prostate Cancer Biospecimen Cohort Study

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REPORT DATE: October 2016

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;
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REPORT DOCUMENTATION PAGE				Form Approved OMB No. 0704-0188	
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1. REPORT DATE October 2016		2. REPORT TYPE Annual		3. DATES COVERED 30 Sep 2015 - 29 Sep 2016	
4. TITLE AND SUBTITLE Prostate Cancer Biospecimen Cohort Study				5a. CONTRACT NUMBER	
				5b. GRANT NUMBER W81XWH-15-2-0062	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) Bettina F. Drake, PhD, MPH E-Mail: drakeb@wustl.edu				5d. PROJECT NUMBER	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) WASHINGTON UNIVERSITY ONE BROOKINGS DR SAINT LOUIS MO 63130-4862 AND ADDRESS(ES)				8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012				10. SPONSOR/MONITOR'S ACRONYM(S)	
				11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited					
13. SUPPLEMENTARY NOTES					
14. ABSTRACT The goal of the study is development of a Prostate Cancer Biorepository Network (PCBN) resource site with high quality and well-annotated urine, blood, and tissue specimens as part of a multi-institutional Department of Defense collaboration. De-identified data, tissue and other biospecimens will then be available through the sites to all prostate cancer investigators to conduct further research. This is a collaborative effort among the sites with no coordinating center and each site will be responsible for maintaining/storing their own data/samples.					
15. SUBJECT TERMS Prostate cancer, disparities, biorepository, active surveillance, high risk					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRMC
Unclassified	Unclassified	Unclassified	Unclassified	8	19b. TELEPHONE NUMBER (include area code)

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1. INTRODUCTION:

The goal of the study is development of a Prostate Cancer Biorepository Network (PCBN) resource site with high quality and well-annotated urine, blood, and tissue specimens as part of a multi-institutional Department of Defense collaboration. De-identified data, tissue and other biospecimens will then be available through the sites to all prostate cancer investigators to conduct further research. This is a collaborative effort among the sites with no coordinating center and each site will be responsible for maintaining/storing their own data/samples.

2. KEYWORDS:

Prostate cancer, biorepository, disparities, active surveillance, high risk

3. ACCOMPLISHMENTS:

What were the major goals of the project?

1. Team Meeting
 - a. Review grant and progress of recruitment in parent study – Year 1, Month 1 – 100% complete
 - b. Team Meetings will occur monthly throughout the award – Year 1-2, Monthly – 100% complete
 - c. Meetings with Tissue Procurement Core – Year 1-2, Monthly – 100% complete
2. Protocol Development
 - a. Meet with Tissue Procurement Core and the Resource Site Coordinator to finalize protocol – Year 1, Month 3 – 100% complete
 - b. Train Recruiter and Data Manager on protocol to use for recruitment and data entry – Year 1, Month 3-4 – 100% complete
3. Regulatory review and Institutional Review Board (IRB)
 - a. Complete and submit forms for regulatory review – Year 1, Month 3-4 – 100% complete
 - b. Complete and submit IRB forms for review – Year 1, Month 3-4 – 100% complete
 - c. Obtain approval for regulatory and IRB forms – Year 1, Month 4 – 100% complete
4. Recruitment
 - a. Active surveillance patients – Year 1, Month 5-12
 - b. High risk patients – Year 1, Month 5-12
 - c. African American patients – Year 1, Month 5-12
 - d. Recontact high risk patients from Prostate Cancer Prospective Cohort– Year 1, Month 6-12
5. PCBN-related travel
 - a. PCBN EAB meetings – Year 1, – 100% complete
 - b. 1-day meeting to present on progress at Integration Panel – Year 1, – 100% complete
6. Pathological review
 - a. Site visits by Dr. Humphrey (urological pathologist) – Year 1, Month 6 – 100% complete
 - b. Regular review by Dr. Sehn – Year 1, Month 6 – 100% complete

What was accomplished under these goals?

1. Grant reviewed and parent study accessed for high-risk patients to recontact. Team meetings and meetings with TPC for study development.
2. Protocol developed and finalized for regulatory submission. Recruiter hired and trained along with data manager.
3. Protocol and application submitted to IRB, and approval letters obtained.
4. Recruitment
 - a. Recruitment started in March of 2016 and there are currently 49 newly diagnosed patients consented.
 - i. Active surveillance patients: 16
Active Surveillance African American patients: 8
 - ii. High risk patients: 23
High risk African American patients: 4
 - b. An amendment to the IRB in recruitment has been submitted to cover patients considered to be “intermediate risk” (Gleason 3+4). This was changed because 65% of patients were being missed, that were considered “low risk” previously in our study, which went on to have treatment.
 - c. Recontacting patients from the Prostate Cancer Prospective Cohort study is in progress.
5. PCBN related travel
 - a. PCBN EAB meetings
1 conference call
1 Scheduled in October/November
6. Pathological review
 - b. Dr. Jennifer Sehn is now currently the pathologist on the study and reviews all slides.

	Prostate Cancer Prospective Cohort Previously Banked Biospecimens	Biospecimen Acquisition March 2016 – October 2016
Plasma/Serum/Cell Pellet***		
Total High-risk	320	21
African American	38	3
Total Active Surveillance	N/A	15
African American	N/A	2
Low risk African Americans (not on Active Surveillance)		4
Total Plasma/Serum/Cell	320	40
Urine		
Total High-risk	N/A	21
African American	N/A	3
Total Active Surveillance	N/A	15
African-American	N/A	2
Low Risk African Americans (not on Active Surveillance)		4
Total Urine	N/A	40
Tissue		
Total High-risk	243	4
African American	26	1
Total Active Surveillance	N/A	0
African-American	N/A	0
Low Risk African Americans (not on Active Surveillance)		2
Total Tissue	243	6
TOTAL SPECIMENS	563	86
***Only serum and cell pellet available on Prostate Cancer Prospective Cohort		

What opportunities for training and professional development has the project provided?

Nothing to Report

How were the results disseminated to communities of interest?

Nothing to Report

What do you plan to do during the next reporting period to accomplish the goals?

Continue recruitment for active surveillance patients, high-risk, and African American patients. Recontact patients from the Prostate Cancer Prospective Cohort and begin recruitment for the “intermediate risk” patients.

4. IMPACT:

What was the impact on the development of the principal discipline(s) of the project?

Nothing to Report

What was the impact on other disciplines?

Nothing to Report

What was the impact on technology transfer?

Nothing to Report

What was the impact on society beyond science and technology?

Nothing to Report

5. CHANGES/PROBLEMS:

Changes in approach and reasons for change

Nothing to Report

Actual or anticipated problems or delays and actions or plans to resolve them

Nothing to Report

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Nothing to Report

Significant changes in use or care of human subjects

Nothing to Report

Significant changes in use or care of vertebrate animals.

Nothing to Report

Significant changes in use of biohazards and/or select agents

Nothing to Report

6. PRODUCTS:

- **Publications, conference papers, and presentations**
Journal publications.
Nothing to Report

Books or other non-periodical, one-time publications.
Nothing to Report

Other publications, conference papers, and presentations.
Nothing to Report
- **Website(s) or other Internet site(s)**
Nothing to Report
- **Technologies or techniques**
Nothing to Report
- **Inventions, patent applications, and/or licenses**
Nothing to Report
- **Other Products**

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

1. Name: Bettina F. Drake, PhD, MPH
Project Role: Principal Investigator
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 3.6
Contribution to Project: Dr. Drake is the lead investigator on this study.
Funding Support: DoD Grant
2. Name: Katina Richardson, MD
Project Role: Recruiter
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 12
Contribution to Project: Dr. Richardson is the recruiter on this study.
Funding Support: DoD Grant
3. Name: Danielle Rancilio, MS, MPH
Project Role: Data Manager
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 3
Contribution to Project: Ms. Rancilio has worked on goals related to this study including data and study management.
Funding Support: DoD Grant

- | | | |
|----|--|---|
| 4. | Name: | Alex Klim, RN, MHS, CCRC |
| | Project Role: | Site Coordinator |
| | Researcher Identifier (e.g. ORCID ID): | |
| | Nearest person month worked: | 1.2 |
| | Contribution to Project: | Mrs. Klim has worked on goals related to study and regulatory management. |
| | Funding Support: | DoD Grant |
-
- | | | |
|----|--|--|
| 5. | Name: | Jennifer Sehn, MD |
| | Project Role: | Pathologist |
| | Researcher Identifier (e.g. ORCID ID): | |
| | Nearest person month worked: | 0.6 |
| | Contribution to Project: | Dr. Sehn serves as will serve as the study pathologist and leads the processing, annotation and storage of prostate biospecimens. In addition, Dr. Sehn works with consultant, Peter Humphrey, when a second opinion would be beneficial in reviewing the pathology. |
| | Funding Support: | DoD Grant |

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

Dr. Jennifer Sehn has replaced Dr. John Pfeifer as the pathologist at the same 5% effort on the study.

What other organizations were involved as partners?

Nothing to Report

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS:

N/A

QUAD CHARTS:

N/A

9. APPENDICES:

None